

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
 (Chapter II of the Patent Cooperation Treaty)
 (PCT Article 36 and Rule 70)

Best Available Copy

Applicant's or agent's file reference 20009WOP00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001416	International filing date (day/month/year) 15 October 2004	Priority date (day/month/year) 17 October 2003
International Patent Classification (IPC) or national classification and IPC		
Int. Cl. <div style="display: flex; justify-content: space-around;"> A61K 38/45 (2006.01) A61P 35/00 (2006.01) C12N 9/12 (2006.01) </div>		
Applicant INTER-K PTY LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 21 sheets, as follows:

☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 15 August 2005	Date of completion of this report 08 February 2006
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE	Authorized Officer

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001416

Box No. 1 Basis of the report

1. With regard to the language, this report is based on:

☒ The international application in the language in which it was filed☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:☐ international search (under Rules 12.3(a) and 23.1 (b))☐ publication of the international application (under Rule 12.4(a))☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:☐ the international application as originally filed/furnished☒ the description:

pages 1-14, 16-38 as originally filed/furnished

pages* 15 received by this Authority on 19 January 2006 with the letter of 18 January 2006

pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* 39-41 received by this Authority on 19 January 2006 with the letter of 18 January 2006

pages* received by this Authority on with the letter of

☒ the drawings:

pages 1/20-20/20 as originally filed/furnished

pages* received by this Authority on with the letter of

pages* received by this Authority on with the letter of

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (specify):☐ any table(s) related to the sequence listing (specify):4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).☐ the description, pages☐ the claims, Nos.☐ the drawings, sheets/figs☐ the sequence listing (specify):☐ any table(s) related to the sequence listing (specify):

* If item 4 applies, some or all of those sheets may be marked "superseded"

Best Available Copy

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001416

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☒ received by this Authority as an amendment* on 5 November 2004
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001416

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-21	YES
	Claims	NO
Inventive step (IS)	Claims 1-21	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-21	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 2001/000677 A

D2: WO 2002/051993A

The invention is to methods for the prophylaxis or treatment of cancer cells including circulating blood cell cancer, by blocking mitogen activated protein kinase (MAPK)-integrin binding interactions with an agent comprising a polypeptide that binds to a binding domain of the MAPK for a β integrin subunit wherein the β integrin subunit is not necessarily expressed by the cancer cells. The invention includes a composition of the said polypeptide and a signal peptide which acts to facilitate the passage of the agent across the outer cell membrane into the cancer cells. The signal peptide comprises the amino acid sequence $\Delta\Delta VALLPAVLLALLA$ or $\Delta\Delta VALLPAVLLALLAP$ and the polypeptide is selected from the following group; RSKAKWQTGTNPLYR, RARAKWDTANNPLYK, RSRARYEMASNPLYR, RSKAKNPLYR, RARAKNPLYK, RSRARNPLYR, KEKLKSQWNNDNPLFK and KEKLKNPLFK.

Novelty (N); Claims 1-21

D1 and D2 each teaches methods of modulating integrin mediated cellular activity using agents capable of inhibiting the binding of MAPK to a binding domain of an integrin, thereby resulting in the inhibition of the growth of cancer cells. The agent or polypeptide is disclosed as comprising a fragment of an integrin subunit and includes the following amino acid sequences, RSKAKWQTGTNPLYR, RSKAKNPLYR, RSKAK or NPLYR. Carrier peptides for transporting delivery of the agent or polypeptide are also taught.

The present invention is distinguished over the prior art in that it was observed that it is not necessary for the integrin to which the MAPK binds to be expressed by the target cells in order to inhibit growth of the cancer cells. Common general knowledge in the art suggests that MAPK were activated remotely from the plasma membrane downstream of integrin transmembrane signalling and did not associate with integrin. D1 and D2 are directed to the finding that MAPK can bind to integrins. In seeking a method for the prophylaxis or treatment of cancer, the skilled addressee would focus on inhibiting the physical association of the MAPK with the integrin in order to down-regulate the activation of MAPK, thus requiring that the target cancer cells express the integrin. The present invention relates to the administration of a polypeptide that binds to a binding domain of a MAPK for a corresponding binding domain of a β integrin subunit in the treatment of cancer, wherein the β integrin subunit is essentially not expressed by the cancer cells. As such the claims 1-21 meet the criteria set forth in PCT Article 33(2) for novelty.

Best Available Copy

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001416

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Inventive Step (IS): Claims 1-21

As above

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

Best Available Copy
Best Available Copy